

## **REMARKS**

### **A. Prior Art Status of US 6,431,174**

In the September 9, 2005 Office Action, the sole rejection is based on 35 U.S.C. § 102(e). The sole reference cited against the pending claims is Assignee's U.S. Pat. No. 6,431,174 which issued August 13, 2002.

The present application has first claim of priority to February 4, 2002 (before the issuance of the '174 patent) and a second claim of priority to September 6, 2002 as a continuation-in-part application.

For the purpose of this response, Applicants' submit the subject matter of the claims are directed to the new matter introduced on September 6, 2002 in Serial No. 10/237,149. The present application is a continuation of the '149 application.

### **B. Inventorship, Assignment and Early Invention**

#### **a. Common Assignee**

As shown on the face of the '174 patent and the declaration filed in the present application, there are common inventors (although not identical inventors) between the '174 patent and the present application. The '174 patent and the present application are commonly assigned to Restore Medical, Inc.

On its face, the '174 patent is assigned to Pi Medical, Inc., St. Paul, MN. This is as appears on the original assignment recorded with the Patent Office at Reel 011037, Frame 0901. Pi Medical changed its name to Restore Medical Inc. A copy of the documents submitted to the Patent Office to record this name change is enclosed as Exhibit A to the Conrad Declaration. The present application (by reason of assignment of its parent application) is assigned to Restore Medical Inc. as appears in the records of this file and as recorded in the PTO Assignment Branch at Reel 013577, Frame 0394 (assignment to Pi Medical, Inc. with subsequent name change to Restore Medical, Inc.). Exhibit A to the Conrad Declaration is the notice of recordation of name change in both the parent of the present application and the '174 patent.

### **C. Earlier Invention**

The invention of the present application was made before the issuance of the '174 patent. Enclosed are the Declarations of John P. Sopp and Brian J. Erickson establishing the invention was made as early as February 2002 (Sopp Ex. A - drawings substantially identical with Figs. 6

and 7 of the present application) and continued in June 2002 (Erickson Ex A - draft product requirements including text incorporated into the present application) up to the filing of the present application.

**D. Rejection Under 35 U.S.C. § 102(e)**

In response to the anticipation rejection, Applicants have amended independent claims 1 and 9 to reflect the implant is placed with its longitudinal axis transverse to an axis of the pharyngeal airway. Since a positioning of an implant is not shown in the '174 patent. Hence, the present amendment overcomes a rejection based on anticipation. "In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." M.P.E.P. § 706.02 (IV).

**E. Use of '174 patent as prior art under 35 U.S.C. §103(a)**

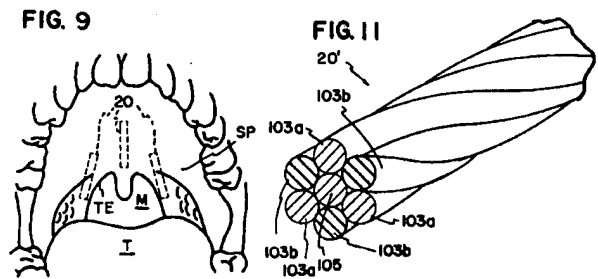
While no rejection is made on the basis of obviousness, Applicants submit the '174 patent is not combinable with any other prior art reference to create such a rejection. "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." 35 U.S.C. § 103 (c)(1).

**a. Amendments and Substantive Remarks Distinguishing Present Claims from Cited Reference**

Notwithstanding the foregoing, and in view of the remarks that follow, Applicants respectfully submit this application is in condition for allowance even if the '174 patent were proper prior art.

**i. Disclosure of Assignee's US 6,431,174**

The '174 patent includes a disclosure of earlier filed applications. As indicated in col. 4, lines 41 – 44, these include Figs. 6 – 15 of the '174 patent which are from Assignee's Ser. No. 09/513,432 filed February 25, 2000 (now U.S. Pat. No. 6,450,169 issued September 17, 2002).



Of these, Fig. 9 shows longitudinal implants 20 in the soft palate. Fig. 11 shows the implant as a braid. Figs. 9 and 11 are reproduced in this Amendment.

The disclosure of the '174 patent also includes a disclosure of a bolus of particulate material in any one of a number of airway tissues including pharyngeal wall tissue. For example, Fig. 14 (reproduced in this Amendment) shows a bolus of such material in the soft palate and Fig. 16 shows such material about to be delivered to the pharyngeal wall.

## ii. Disclosure of the Present Application

Beginning on page 9, line 6 of the present application, transversely placed longitudinal implants are shown and described in the pharyngeal wall to treat obstructive sleep apnea. Page 15, beginning at line 31, describes placement of implants parallel to the axis of the pharyngeal wall. Representative figures from the present application are reproduced in this Amendment.

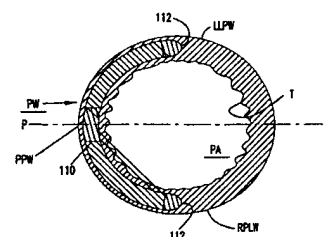
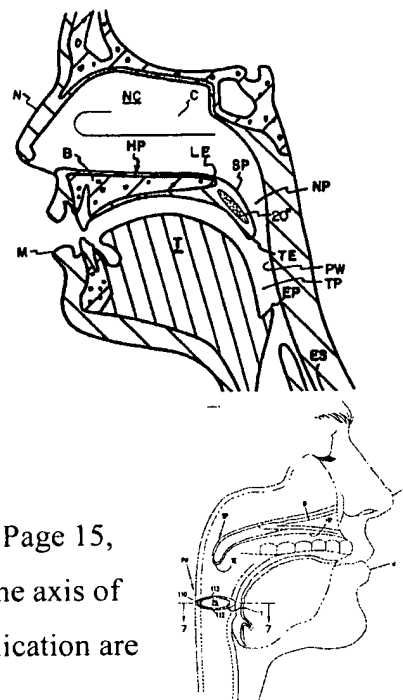
In addition to the specific orientations and numbers of implants shown, the disclosure of the present application includes numerous other teachings not shown or suggested in the cited references. For example, the disclosure teaches:

- How to size an implant for the specific anatomy challenges of the pharyngeal airway (see, e.g., discussions beginning on page 9, line 15 and page 15, line 18);
- How to identify the target cite of for placement of implants (see, e.g., discussions beginning on page 11, line 12);
- The structural requirements of the implant to resist pharyngeal wall collapse after implantation discussions beginning on page 14, line 8).

### b. Claims for Longitudinal Implants Based on the '174 Patent's Disclosure

Applicants agree the disclosure of the '174 patent supports the concept of placing a longitudinal implant in the pharyngeal wall. Indeed, patents claiming priority to the '174 patent have issued with such claims. For example:

- U.S. Pat. No. 6,546,936 (claiming the same priority as the '174 patent) has issued with the following claim 1:



A method for treating an upper airway condition of a patient characterized at least in part by a reduced stiffness of tissue of a pharyngeal wall of said patient, said method comprising:

selecting an implant sized to be implanted into said tissue of said pharyngeal wall, said implant having characteristics for said implant, at least in tissue of said pharyngeal wall of said patient, to stiffen said tissue of said pharyngeal wall;

implanting said implant into said tissue of said pharyngeal wall to stiffen said tissue.

- U.S. Pat. No. 6,742,524 (claiming the same priority as the '174 patent) has issued with the following claim 1:

A method for treating an upper airway condition of a patient, said method comprising:

selecting an implant sized to be implanted into a tissue of a pharyngeal wall of said patient, said implant including a longitudinal permanent implant of biocompatible material selected to stiffen said tissue of said pharyngeal wall; and

implanting said implant into said tissue of said pharyngeal wall to stiffen said tissue.

Claim 2 of the '524 patent states the implant can be a braid of fibers.

- U.S. Pat. No. 7,017,582 (the parent to the present application) issued with the following claim 1:

A method for treating obstructive sleep apnea of a patient by treating a pharyngeal airway having a pharyngeal wall at least partially surrounding and defining said airway, said method comprising:

selecting an implant dimensioned so as to be implanted at a mucosal layer of said pharyngeal wall, said implant having a longitudinal dimension;

said implant having mechanical characteristics for said implant to stiffen said pharyngeal wall to resist radial collapse; and

implanting said implant into said pharyngeal wall with said longitudinal dimension extending at least partially around said pharyngeal wall, transverse to a longitudinal axis of said pharyngeal airway.

**c. Terminal Disclaimer**

Applicants do not admit the claims of the present application are obvious variants of the foregoing. However, in order to expedite prosecution, Applicants submits herewith a terminal disclaimer of a patent issuing on the present application with each of U.S. Pat. No. 7,017,582; U.S. Pat. No. 6,546,936 and U.S. Pat. No. 6,742,524.

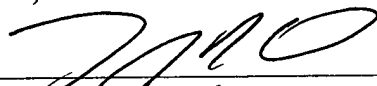
**F. Conclusion**

Applicants respectfully submit this application is now in condition for allowance. Reconsideration and notice of allowance are solicited.

Respectfully submitted,

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